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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
1001.2192101

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on April 19, 2010

Signature /JoAnn Lindman/

Typed or printed name JoAnn Lindman

Application Number	Filed
10/601,952	June 23, 2003

First Named Inventor: Karl A. Jagger

Art Unit	Examiner
3731	Sonnett, Kathleen C.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 36,926
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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Telephone number

April 19, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Appellants have carefully reviewed the Final Office Action of November 19, 2009 and the Advisory Action of March 4, 2010. Currently, claims 1-30 are pending in the application and claims 1-8 and 21-30 have been withdrawn. Claims 9-20 have been rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 9, 13, and 18 were rejected under 35 U.S.C. 103(a) as obvious over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868). Appellants respectfully traverse the rejection for at least the reasons that the combinations of references do not each all the claim limitations, as is required to establish a *prima facie* case of obviousness as applied to claim 9 and the Final Office Action does not provide a proper motivation for the combinations. The remaining rejections of claims 10-20 depend upon the rejection of claim 9 in view of these references. As such, these claims are believed to be allowable over these references.

The Final Office Action acknowledges that: "Shortt fails to disclose crimping the stent onto the balloon as the step of crimping is done prior to the stent being placed over the balloon according to the disclosure of Shortt." The Final Office Action also acknowledges that: "Shortt also fails to disclose a maximum outer diameter of the distal section of the balloon that is no greater than the initial diameter of the stent since the balloon includes a distal pillow." The Final Office Action further acknowledges that: "Shortt does not expressly disclose that the diameter of the first portion is greater than or equal to the inner diameter of the second section." The Final Office Action still further acknowledges: "Shortt also fails to disclose a maximum outer diameter of the distal section of the balloon that is no greater than the initial diameter of the stent due to the presence of the distal balloon pillow."

The Final Office Action characterizes Shortt as disclosing a method for fabricating a balloon catheter stent deployment system comprising "providing a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft

near the distal end thereof (see Fig. 2)". Appellants respectfully disagree. Fig. 2, reproduced below for convenience, discloses a catheter assembly comprising an inner tube and an outer tube joined co-terminally at their respective distal ends, illustrated within the section labeled "4th TFE". There is no separate balloon element and thus no attachments between the distal and proximal respective ends of a balloon element and the (distally co-terminal) distal ends of the inner and outer tubes.

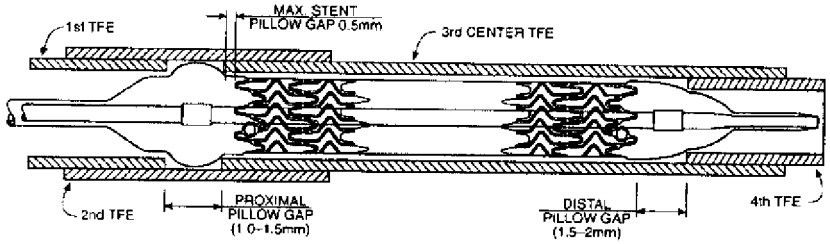

FIG._2 (PRIOR ART)

It should also be noted that the rejections over Shortt relies primarily upon the disclosure of unidentified prior art rather than disclosure of the invention of Shortt itself. To the extent that claim 9 has been rejected over the references in view of the invention of Shortt, the form of the resulting embodiment as depicted in Figs.7A and 7B relies upon similar proximal and distal pillows although formed in a different manner. The description of Fig. 2 in particular and the prior art in general uses the abbreviation TFE to characterize sheaths which form the containment system employed. TFE is explicitly identified by Shortt as tetrafluoroethylene at col. 2, lines 12-15. Tetrafluoroethylene has a boiling point of -76.3 °C. Although Shortt does not disclose the temperature of the "hot air" employed to heat set the outer tube thereby forming the balloon in the unidentified reference, Shortt does disclose that temperatures of about 93 °C are typical for use with stent/balloon assemblies and temperatures up to 180 °C may be used. Accordingly, the disclosure relied upon by the Final Office Action teaches that a heat set step is carried out at a temperature of about 169-256 °C above the boiling point of the tetrafluoroethylene mold material thereby indicating that the by then gaseous sheaths are incapable of imposing fixed dimensions upon the outer tube as it expands under the influence of internal pressure. One of ordinary skill in the art would not turn to such a process/gaseous containment apparatus to create a molded balloon catheter absent some advantage of that prior art unidentified by Shortt and any modification which employs a conventional solid mold would impermissibly alter the principle of operation of the unidentified prior art reference relied upon

by the Final Office Action. (See MPEP § 2143.01 Part VI.) The Final Office Action explicitly relies upon the background disclosure of col. 2 and tetrafluoroethylene (TFE) sleeves at page 3.

With respect to the order of the steps of crimping the stent and placing the stent over the balloon, Shortt specifies that step of crimping is done prior to the stent being placed over the balloon (col. 2, lines 54-55), but is not yet crimped to fix the position of the stent relative to the balloon catheter assembly. Instead, the Shortt specifies that stent may be positioned on the balloon between the markers. Were the stent to be crimped directly to the balloon as suggested by the proposed combination of Shortt and Morales, the stent would not be positionable between the markers after crimping as taught by Shortt. One of ordinary skill in the art would not be motivated to give up this positionability by making the modification proposed to prevent the stent from sliding off of the catheter when the catheter is advanced because the stent delivery system of Shortt already has an adequate means of retaining the stent relative to the delivery system. As depicted in Fig. 2, there appears to be no significant risk that the stent would be dislodged from the catheter of Shortt during translation.

With respect to the maximum outer diameter of the distal section of the balloon of Shortt, it will be seen in the cited Fig. 2, reproduced above, that the diameter of the distal section of the balloon formed by the prior art disclosed by Shortt, and also in the embodiment produced by the method of Shortt, is larger than the outer diameter of the stent of Shortt, especially since the "initial diameter" of the stent, as recited in pending claim 9 is that of the crimped stent of the unidentified prior art reference of Shortt. Modification by pre-crimping the stent as taught by Morales does not appear to alter the expected enlargement of those portions of the balloon distal of the crimped stent upon inflation and heat setting.

Further, the Final Office Action refers to Figures 15 and 16 of Hanson with the unsupported assertion that Hanson discloses that it is well known to include only a proximal balloon pillow. The absence of a distal pillow is said to be supported by the difference between Figs. 15 and 16 and Figs. 17 and 18 which include explicit provision for forming an enlarged region in the vicinity of distal dam 20; however the processes disclosed by Shortt explicitly inflate the balloon portions of the outer tube which would create distal pillows in the region distal to end 34 of split inner sleeve 28 and outer sleeve 40 were those sleeves to be employed contrary to the disclosure of Shortt. Otherwise, the inflation and heat setting operations taught by Shortt would continue to produce proximal and distal enlarged portions having a maximum

outer diameter greater than the initial outer diameter of the stent as recited in claim 9. It appears that the Final Office Action is proposing a combination of isolated features of references which might, under some circumstances, be capable of reproducing Appellants' invention without providing proper motivation for either the selection or the combination of those elements. This "reasoning" is reflected in the Advisory Action which states:

> "However, it is the examiner's position that, in view of the teachings of Hanson that no distal dam (pillow) is necessary, one skilled in the art would have found it obvious to modify the stepped enclosure of Shortt so that no distal dam (pillow) is formed since the stepped enclosure is responsible for forming the dams (pillows)"

It should be noted that Shortt explicitly characterizes the method of the unidentified prior art as forming a distal pillow and further relies upon the formation of proximal and distal pillows to reduce the risk of relative movement between the balloon and the stent. (Col. 2, lines 4-10.) Removing the distal pillow would further impermissibly alter the operating principle of Shortt (MPEP 2143.01, VI.) Further, the Advisory Action incorrectly equates the pillows in balloon 20 produced by the heat set step of Hanson with the dams 18 and 20 which form a portion of shaft 13 of catheter 20 about which the balloon is molded. Thus it is not the stepped external enclosure of Hanson, but rather the internal dams which are responsible for the formation of the pillows in the process steps of Hanson which does not employ inflation. Again, the Advisory Action does not provide a motivation for the combination of references other than replicating the invention of claim 9 and ignores the teachings of the references to do so.

Additionally, the Final Office Action, in the Response to Arguments, incorrectly substitutes a definition of the adverb "near" for the adjectival definition and then incorrectly parses the incorrect definition of "near" provided by dictionary.com. That definition, the second adverbial definition provided by that source, "at, within, or to a short distance" comprises a series of modifiers for the phrase "short distance" and thus in common English usage indicates "at a short distance"; "within a short distance"; or "to a short distance". The first adjectival definition provided by dictionary.com is: "being close by; not distant" and thus the common adjectival definition of "near" is understood to distinguish from "at" by consistently indicating the presence of a relatively small separation. In this context, the distinction is relevant because claim 9 recites points of connection between the balloon and the inner and outer shafts which are

near their respective distal ends. The disclosure of Shortt does not include a separate balloon attached to an inner and an outer shaft, but rather discloses a two part catheter assembly comprising an inner shaft connected at its distal end to the distal end of a second shaft. A distal portion of said second shaft will become the balloon portion of the stent catheter following heating and expansion within the mold of Shortt. Thus prior art Fig. 2 of Shortt discloses first and second tubes joined at their respective distal ends and does not disclose a balloon joined to an outer shaft and more particularly does not disclose "an inner tubular shaft disposed within an outer tubular shaft ... and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof", as recited in independent claim 9 for at least the reasons that there is no separate balloon to be joined to the outer tube "near" the distal end of the outer tube and that the portion of the outer tube which eventually becomes the balloon is joined co-terminally with the inner tube rather than "near" the proximal end of the balloon. The distal end of the outer tube is joined at the distal end of the inner tube and distal of the distal end of the eventual balloon portion of the outer tube.

The Final Office Action ignores the teaching of the disclosure Shortt with regard to the need for a distal pillow and proposes modifications to Shortt, without motivation therefor, which impermissibly alter the operating principle of Shortt. Accordingly, the combinations of references do not each all the claim limitations, as is required to establish a *prima facie* case of obviousness and the Final Office Action does not provide a proper motivation for the combination.

Appellants respectfully request that the rejection of independent claim 9 and of claims 10-20, which depend therefrom and also are believed to be nonobvious, be overruled.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: April 19, 2010

/glenn m. seager/

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